### Progress report 2015

## **Department of Health Care Safety Management**

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## **■** Overview of the Department

The Department for the Study of the Safety of Healthcare was established in December 2005.

Media reports on medical mishaps and disputes over medical care increased abruptly starting in 1999, public distrust of the medical establishment increased, and the medical care system faced collapse. However, efforts have been made to shore up the medical care system and to restore trust in the medical establishment through the dedicated work of the state, the medical establishment, and related fields to rebuild public trust in the medical establishment. For 10 years, the Department has responded to demands from society and it has looked at the realities of medical mishaps and disputes over medical care. While doing so, the Department has proposed better legislation from the perspective of the patient, medical personnel, and society as a whole and it has encouraged and facilitated mutual understanding based on dialogues between patients and medical personnel.

Starting this year, the Department will begin to examine the safety of next-generation medical care in addition to previous topics it has examined.

Medical care must move forward despite risks. Medical personnel and society as a whole need to be interested in and understand advanced medical care. The Department seeks to study cutting-edge technologies and systems that are appearing in medical settings, such as transplantation and implantation, artificial organs, and new medical devices. The Department also seeks to study, assess, and improve the quality and safety of medical care in order to facilitate future medical care.

#### Areas of Research

The Department is involved in the following research, education, and programs.

#### 1. Research

- Basic research on true solutions to medical mishaps, disputes over medical care, and complaints about medical care
- •Research on mutual understanding based on dialogues between patients and medical personnel and dialogues between the medical establishment and society as a whole
- Research on establishment of systems to ensure the safety of medical care in order to facilitate advanced medical care
- Team training in transplantation and implantation

#### 2. Education

- •Study of safety in medical care and training in that area in the School of Public Health
- •Lectures and talks to legal professionals, the medical establishment, welfare providers, and personnel in related fields regarding topics such as patient education, education to improve counseling, and information about advanced medical care
- Fostering personnel to counsel individuals with complaints about their medical care
  - \* The Project to Fully Support the Operations of Centers to Improve the Safety of Medical Care

Centers to Improve the Safety of Medical Care have been established in individual prefectures and major metropolitan areas pursuant to the provisions of the Medical Service Act. The Project to Fully Support the Operations of Centers to Improve the Safety of Medical Care provides training for Center personnel (a

project supported by grants from the Ministry of Health, Labour and Welfare).

#### 3. Programs

The Department is involved in a range of efforts, from conducting teamwork training in advanced medical care at medical facilities to providing support to establish a system to provide counseling regarding complaints about community-based care, e.g. centers to improve the safety of medical care and integrated community-based care. The Department is creating a system to identify issues in care settings, to examine those issues, to inform personnel in care settings of those issues, and to continually assist personnel in those settings. The Department is also fostering personnel.

The Department has been commissioned by the Ministry of Health, Labour and Welfare to implement the Project to Fully Support the Operations of Centers to Improve the Safety of Medical Care. Centers to Improve the Safety of Medical Care are organizations that provide a host of suggestions and information about the safety of medical care, primarily in the form of medical counseling for patients. Centers to Improve the Safety of Medical Care have been established in individual prefectures and urban areas where public health centers were needed (there are 381 Centers nationwide), and these Centers provide the second tier of medical care [Japan has 3 tiers of medical care: the first tier (healthcare and welfare services provided by a municipality), the second tier (general care provided by different areas within a prefecture), and the third tier (specialized care provided by a prefecture)]. The activities of the Centers are not limited to medical counseling and preventing disputes over medical care (e.g. addressing complaints). Depending on the region and size of the Center, Centers offer various services, such as liaising between the patient and a medical facility, providing medical information to patients, liaising with and sharing information among medical facilities. The Project to Fully Support the Operations of Centers to Improve the Safety of Medical Care supports the operations of centers to improve the safety of medical care through efforts such as coordinating regional efforts nationwide, conducting training, creating instructional materials, disseminating information on its website, and conducting surveys. The Project will continue its national efforts through workshops, seminars, and information on its website in order to encourage and facilitate the efforts of centers to improve the safety of medical care and to inform the public

of the efforts by those centers. The Project will also use various approaches, such as tailored seminars for local residents and training for personnel, to accomplish its goals.

### **■** Prospects for the Future

## 1. Exploring ways to ensure the safety of medical care in order to facilitate future medical care

Determining what is needed to persuade and reassure patients undergoing advanced medical care (e.g. regenerative medicine).

- The safety of advanced medical care
   What informed consent entails and methods of
   obtaining informed consent, teamwork training, the role
   of the transplant coordinator
- The safety of medical care in relation to the development and improvement of medical devices
   Methods for the safety and safe use of medical devices to facilitate advanced medical care

## 2. Study of and support for public efforts to ensure reliable and safe medical care

Conducting studies needed to ensure the safety of medical care at medical facilities as well as the safety of community medicine and integrated community-based care

•Encouraging and facilitating mutual understanding of patients and medical personnel

Addressing complaints about medical care, the effectiveness of efforts to improve counseling, patient education, and efforts to educate the public

### [Achievements in 2015]

### **■** Joint Research & Commissioned Research

- The 2015 Project to Fully Support the Operations of Centers to Improve the Safety of Medical Care, supported by grants from the Ministry of Health, Labour and Welfare
- Yasushi Kodama. 23<sup>rd</sup> Grant for a Joint International Study (2014) from the Pfizer Health Research Foundation, "A Study of the Safety of Medical Care and the System to Retrain Physicians in the US" Study Chair, December 2014–November 2015

# ■ Research facilitated by grants-in-aid for scientific research offered openly

 Masaki Anraku. Grant-in-aid for scientific research from the Ministry of Health, Labour and Welfare (Basic Research C), "Elucidation of the mechanisms of

- post-transplant pulmonary dysfunction with a focus on histone-related vascular endothelial dysfunction," 2014–17.
- Yasushi Kodama. Grant-in-aid for scientific research from the Ministry of Health, Labour and Welfare, "A Study on Improving the Operation of Centers to Improve the Safety of Medical Care" (Study Chair Yasushi Kodama), 2015–16.
- 3. <u>Yasushi Kodama.</u> Grant-in-aid for scientific research from the Ministry of Health, Labour and Welfare, "Drafting Legislation to Create a "Just Culture" with regard to Medical Mishaps: An analysis of the causes of medical mishaps and legislation to prevent those mishaps from recurring" (Study Chair: Futoshi Iwata), Investigator, 2015–16.